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| 09/331,631      | 06/21/1999  | JOHN MICHAEL MANNERS | CULLN23.001A        | 1902             |

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KNOBBE MARTENS OLSON & BEAR  
620 NEWPORT CENTER DRIVE  
SIXTEENTH FLOOR  
NEWPORT BEACH, CA 926608016

EXAMINER

ROBINSON, HOPE A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1653

72

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/331,631**

Applicant(s)  
**Manners et al.**

Examiner  
**Hope Robinson**

Art Unit  
**1653**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Sep 17, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3, 11-23, 30, 31, 34, 36, 37, and 39-42 is/are pending in the application.
- 4a) Of the above, claim(s) 12, 14, 15, 31, 34, 36, 37, 39, and 40 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 11, 13, 16-21, 41, and 42 is/are rejected.
- 7) ☒ Claim(s) 1, 16, 17, 20-23, 30, and 42 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jun 21, 1999 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. Applicant's response to the Office Action mailed March 14, 2001 in Paper No. 11 on September 17, 2001 is acknowledged.
2. Claims 1, 3, 13, 16, 17, 20, 34 and 42 have been amended. Claim 42 has been added. Claims 1-3, 11-23, 30, 31, 34, 36, 37, 39, 40 and 41-42 are pending. Claims 1-3, 11, 13, 16-23, 30 and 41-42 are under examination.
3. Amended claim 34 is withdrawn from consideration as directed to a non-elected invention. Based on PCT Rules, the application was restricted to a product, method of making the product and method of using the product. Claim 34 as amended recites an alternate method of using the product as claim 13 recites the elected method of using the product "a method of controlling microbial infestation of a plant" which differs from a method of "inhibiting microbial infestation of a plant" having a different outcome. It is noted that page 4 of applicant's response states that claim 34 has been amended to recite "a method of controlling microbial infestation of a plant, the method comprising : treating said plant with an amount of the composition according to claim 11 to reduce or stop microbial infestation of the plant", however, this is not recited in the claim (see page 2 of the amendment filed September 17, 2001).

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4. The following grounds of rejection are applicable :

***Claim Objection***

5. Claims 1, 16, 17, 20-23, 30 and 42 are objected for the following reasons: claim 1 is objected to because the claim recites : SEQ ID Nos: 37-39" which is inconsistent with the notation recited in the pending claims, see for example, claim 17 which recites "SEQ ID NOS:34-36" which is the compliant with the sequence rules. See also the inconsistency between claims 1 and 3 as claim 3 recites an isolated or purified protein and claim 1 does not have the qualifiers "isolated or purified" which is necessary. Note also the inconsistency with regard to a space or no space between the colon and the number. See for example claims 1, 3 and 21 where the sequence notation has this space and claims 16, 17 and 22 where no space is provided. It is suggested that applicant use a uniformed format throughout the claims of one of these options ("SEQ ID NO:1 or SEQ ID NO: 1). The claims are also objected to because of the inconsistency of reciting "Claim 1" and "claim 1", see for example claims 11 and 13 where it is recited as "claim 1" and claims 17, 20, 21 and 42 where it appears as "Claim 1" (see also claim 23). A unified format of either lower case or upper case lettering is suggested.

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***Drawings***

6. The drawings filed on June 21, 1999 remain objected to because Figure 13 and 15 are missing a portion of the Western Blot. See also the Draftsperson's Review Comments.

Correction is required.

7. The amendment filed September 17, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: claim 1 has been amended to read that "X is any amino acid residue other than cysteine". The specification provides no support for this amendment see for example pages 4 and 10 where it is disclosed that "X is any amino acid residue".

Applicant is required to cancel the new matter in the reply to this Office action.

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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8. Claims 1, 2, 11, 13 and 17-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 and the dependent claims hereto introduced new matter into the claims because it is recited in item (a) "X is any amino acid residue other than cysteine". The specification provides no support for this amendment see for example pages 4 and 10 where it is disclosed that "X is any amino acid residue".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 16, 21 and 41-42 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 16 is indefinite because of the recitation of "identifying in a known sequence or designing an amino acid sequence" as the claimed method does not provide any steps as to how to "identify in a known sequence". The claim is further indefinite with regard to "identifying in a known sequence", to whom is the sequence known? The claim is also indefinite as it is not apparent which residues would or would not be substituted and in what positions. The dependent claims are also included in this rejection.

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Claim 21 remains indefinite because in the sequence listing recites residues 29 to 94 for SEQ ID NO: 23 which only has 33 residues based on the raw sequence listing also note that residues 31-85 is recited as SEQ ID No: 24 which should be SEQ ID No: 25.

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claim 1 remains rejected under 35 U.S.C. 102 (a) as being anticipated by Tatar et al. (EP 093652, November 9, 1996).

Tatar disclose peptides used to vaccinate against *E. coli* enterotoxins. In addition, Tatar disclose the sequence contained in SEQ ID No: 39 with the formula C3XC12XC3XC wherein X is any amino acid and C is cysteine, with a 100% sequence identity. Therefore, the limitation of the claim is met by this reference (see sequence alignment and pages 1-2 of the reference).

11. Claim 1 remains rejected under 35 U.S.C. 102 (a) as being anticipated by Voerman (WO 96/13585, May 9, 1996).

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Voerman disclose protease inhibitors obtainable from leeches. Voerman also disclose a medicament and pharmaceutical preparations. Voerman further disclose the sequence contained in SEQ ID No: 37 with a 100% sequence identity where the sequence is C3XC10XC3XC, wherein X is any amino acid and C is cysteine (see the alignment and abstract). Therefore, the limitation of the claim is met by this reference (see sequence alignment and pages 1-2 of the reference).

12. Applicant's arguments filed on September 17, 2001 in Paper No. 11 have been fully considered but were not persuasive. Note that the above amendment introduced new matter into the claims, thus, the rejections under 35 U.S.C. 102(a) remains. With regard to the rejection under 35 U.S.C. 102(a) the response states that neither Tartar et al. or Voerman et al. teach that X is any amino acid residue other than cysteine. As no support for the amendment to the claim was found in the instant specification, the rejection remains because the references are still relevant for the reasons stated above. Regarding the rejection under 35 U.S.C. 112, second paragraph, claim 16 is indefinite as the amendments to the claim resulted in new grounds of rejections. Furthermore, claim 21 remains indefinite as to the number of amino acid residues. It is noted that applicant's response states that the amendment filed December 8, 2000 amended the claims, however, only claim 19 was amended, claim 21 still recites the incorrect sequence identifiers. Thus, the rejections have been maintained.



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*Conclusion*

13. Applicant's amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Claim 3 is free of the prior art.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday and Wednesday-Friday from 9:00 am to 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS 

Patent Examiner



KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER